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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,032	11/03/2003	Hani Sabbah	1059.00096	3424

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,032	SABBAH ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *3-5 and 8-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 6 and 7 are under examination in the instant office action.

Claims 3-5 and 8-14 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected groups of inventions. Applicant timely traversed the restriction requirement in the reply filed on 1/18/2006. This application contains claims 2-5 and 8-14, drawn to invention(s) nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6 and 7 remain rejected under 35 U.S.C. 102(e) as being anticipated by US 6,387,369 (Pittenger et al) as explained in the prior office action and repeated herein.

Claims are directed to a method of treating head failure, improving cardiac function and enriching or regenerating damaged myocardium wherein the method comprises step of administering stem cell products to a heart in need of treatment or to a damaged myocardium stem cell products. Some claims are further drawn to administering the stem cell products intravenously, intracoronary or directly to the heart.

US 6,387,369 (Pittenger et al) discloses a method for producing cardiomycestes *in vivo* wherein the method comprises step of administering stem cell products such as MSCs directly to a heart (col. 6, line 31) or to directly into the damaged portion of myocardium (col. 2, lines 28-29). The cited patent teaches that MSC therapy can be provided by several routes of administration including intravenously, intracoronary or directly to the heart (col. 4, lines 49-68). The cited reference anticipates the claimed invention because it teaches method comprising identical active step and identical structural elements as required by the claimed invention and, therefore, the effects are identical as disclosed and as intended.

Claims 1, 2, 6 and 7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Tomita et al. (IDS reference; Circulation, America heart Association. October 1998. Vol.98, NO. 17, Suppl. 27, pages 1-220) as explained in the prior office action and repeated herein.

Claims are directed to a method of treating head failure, improving cardiac function and enriching or regenerating damaged myocardium wherein the method comprises step of administering stem cell products to a heart in need of treatment or to a damaged myocardium stem cell products. Some claims are further drawn to administering the stem cell products intravenously, intracoronary or directly to the heart.

The cited reference by Tomita et al. discloses a method of treating head failure, improving cardiac function, enriching or regenerating damaged myocardium wherein the method comprises step of administering stem cell products such as mesenchymal stem cells (MSCs) directed to heart or to damaged myocardium. The reference teaches that transplantation of MSCs improved infracted heart function. Thus, the cited reference anticipates the clamed invention.

Response to Arguments

Applicants' arguments filed 5/17/2006 have been fully considered but they are not persuasive.

Main applicant argument with respect to claim rejection under 35 U.S.C. 102(e) as being anticipated by US 6,387,369 (Pittenger et al) or with respect to claim rejection under 35 U.S.C. 102(b) as being anticipated by Tomita et al. is directed to the idea that the cited references disclose administration of stem cells themselves for improving cardiac functions but not administration of secretions from stem cells found in stem cells containing supernatant (se response page 2, par. 2 and see response page 4, par. 2). Yet, the claimed invention is directed to administration of some generic "stem cell products" wherein the claimed product is not characterized as being secretions formed by stem cells and/or as being supernatant separated from stem cells as argued. Moreover, the specification describes injections of stem cells themselves as intended for improving cardiac function and/or for transplantation into myocardium (specification pages 14, lines 9-11).

Thus, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "supernatant" or "secretions") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, the compositions with MSCs used for administration in the methods of the cited references are reasonably believed to contain at least some secretions or extracellular matrices of mesenchymal

stem cells (MSCs) within the broadest reasonable meaning of the claimed term "stem cell products".

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

July 25, 2006

VERA AFREMOVA

PRIMARY EXAMINER